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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/682,161	07/30/2001	Frank Hetzel	P51165	7260

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EXAMINER	
MORGAN, ROBERT W	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/682,161	HETZEL ET AL.	
	Examiner	Art Unit	
	Robert W. Morgan	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/6/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 1/9/04 has been entered and acknowledged.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al. in view of "Base Ten Systems Completes Acquisition of Almedica Technology Group From Almedica International" by Business Wire.

As per claim 1, Colon et al. teaches a registration and sample ordering for the blinded, randomized testing of samples of a product at one or more sites, the system comprising:

i) a remotely accessible electronic database (see: column 3, lines 14-23) programmed to:

a) run real-time or batch data processes (see: column 3, lines 29-31) ,

b) process at least two call flows (see: column 3, lines 14-23),

c) receive and process test subject registration data (see: column 9, lines 41-43),

d) randomize subjects (see: column 3, lines 14-23).

Colon fails to explicitly teach:

e) determine when study numbers are fulfilled and thereafter lock out additional subjects; and

ii) said database being linked to an interactive electronic ordering and tracking system for supplying samples to one or more sites, said ordering system having an electronic randomizing operation for randomizing and individualizing samples based on prior subject randomization.

However, Colon et al. teaches that the Internet network server computer (13, Fig. 1) executes the eligibility parameter of study and assigns patients to a particular study strategy according to clinical study protocol (see: column 6, lines 39-60). The Examiner considers the clinical study protocol to include the determination of a fulfilled study number so that prescriptions are not received which are outside the parameters of the study (column 6, lines 58-60). Therefore, it would have been obvious to include determining when study numbers are fulfilled and thereafter lock out additional subjects within the method and system for conducting clinical trials as taught by Colon et al. with the motivation of providing accurate records regarding the number participants involved a particular study thereby permitting precise and correct results to the study.

Colon et al. fails to also teach an interactive electronic ordering and tracking system for supplying samples to one or more sites, said ordering system having an electronic randomizing operation for randomizing.

Business Wire teaches Base Ten a fully integrated clinical supply chain management solution that includes inventory control, electronic batch records, manufacturing automation, trial design, labeling, packaging, randomization distribution and return management (see: paragraph 2). The Examiner considers the randomization distribution process to include an electronic randomizing operation for randomizing individual samples to one or more sites.

One of ordinary skill in the art at the time the invention would have found it obvious to include Base Ten's clinical supply chain management system as taught by Business Wire within the method and system for conducting clinical trials as taught by Colon et al. with the motivation of serving customer more broadly, and helping them bring pharmaceutical products to market more quickly (see: Business Wire: paragraph 4).

As per claim 2, Colon et al. teaches a computer-based method for carrying out blinded, randomized testing of samples of a product at one or more sites, the method comprising:

i) a remotely accessing an electronic database (see: column 3, lines 14-23) programmed to:

a) run real-time or batch data processes (see: column 3, lines 29-31),

b) process at least two call flows (see: column 3, lines 14-23),

c) receive and process test subject registration data (see: column 9, lines 41-43),

d) randomize subjects (see: column 3, lines 14-23).

Colon fails to explicitly teach:

e) determine when study numbers are fulfilled and thereafter lock out additional subjects; and

ii) linking said database interactively to a second electronic system programmed to accept orders for and track distribution of samples to be used at one more sites, said sample ordering system having an electronic randomizing operation for randomizing and individualizing samples based on prior subject randomization.

However, Colon et al. teaches that the Internet network server computer (13, Fig. 1) executes the eligibility parameter of study and assigns patients to a particular study strategy

according to clinical study protocol (see: column 6, lines 39-60). The Examiner considers the clinical study protocol to include the determination of a fulfilled study number so that prescriptions are not received which are outside the parameters of the study (column 6, lines 58-60). Therefore, it would have been obvious to include determining when study numbers are fulfilled and thereafter lock out additional subjects within the method and system for conducting clinical trials as taught by Colon et al. with the motivation of providing accurate records regarding the number participants involved a particular study thereby permitting precise and correct results to the study.

Colon et al. also fails to teach a second electronic system programmed to accept orders for and track distribution of samples to be used at one more sites, said sample ordering system having an electronic randomizing operation for randomizing.

Business Wire teaches Base Ten a fully integrated clinical supply chain management solution that includes inventory control, electronic batch records, manufacturing automation, trial design, labeling, packaging, randomization distribution and return management (see: paragraph 2). The Examiner considers the randomization distribution process to include an electronic randomizing operation for randomizing individual samples to one or more sites.

The motivation of combining the teachings of Business Wire within the system and method as taught by Colon et al. are discussed in the rejection of claim 1, and incorporated herein.

As per claim 5, Colon et al. teaches a registration and sample ordering for the blinded, randomized testing of samples of a product at one or more sites, the system comprising:

i) a remotely accessible electronic database (see: column 3, lines 14-23) programmed to:

a) run real-time or batch data processes (see: column 3, lines 29-31) ,

b) process at least two call flows (see: column 3, lines 14-23),

c) receives and process test subject registration data (see: column 9, lines 41-43),

d) randomize subjects (see: column 3, lines 14-23).

Colon et al. fails to explicitly teach:

e) lock out new subjects when study numbers are fulfilled; and

ii) an interactive electronic ordering and tracking system for supplying samples to one or more sites, said ordering system having an electronic randomizing and individualizing samples based on prior subject randomization.

However, Colon et al. teaches that the Internet network server computer (13, Fig. 1) executes the eligibility parameter of study and assigns patients to a particular study strategy according to clinical study protocol (see: column 6, lines 39-60). The Examiner considers the clinical study protocol to include the determination of a fulfilled study number so that prescriptions are not received which are outside the parameters of the study (column 6, lines 58-60). Therefore, it would have been obvious to include determining when study numbers are fulfilled and thereafter lock out additional subjects within the method and system for conducting clinical trials as taught by Colon et al. with the motivation of providing accurate records regarding the number participants involved a particular study thereby permitting precise and correct results to the study.

Colon et al. fails to also teach interactive electronic ordering and tracking system for supplying samples to one or more sites, said ordering system having an electronic randomizing.

Business Wire teaches Base Ten a fully integrated clinical supply chain management solution that includes inventory control, electronic batch records, manufacturing automation, trial design, labeling, packaging, randomization distribution and return management (see: paragraph 2). The Examiner considers the randomization distribution process to include an electronic randomizing operation for randomizing individual samples to one or more sites.

The motivation of combining the teachings of Business Wire within the system and method as taught by Colon et al. are discussed in the rejection of claim 1, and incorporated herein.

As per claim 6, it repeats the subject matter of claim 2, on a "machine-readable medium" rather than a series of steps. As the underlying processes of claim 2 has been shown to be obvious in view of the teachings of Colon et al. and Business Wire in the above rejections of claim 2, it is readily apparent that the system disclosed by Colon et al. and Business Wire includes the computer program to perform these functions. As such, these limitations are rejected of the same reasons given above for method claim 2, and incorporated herein.

As per claim 7, Colon et al. teaches a database host computer (11, Fig. 1) and Internet database input forms (40, Fig. 3) used to communicate between the Internet server (13, Fig. 1) and the remote site computer (17, 18, and 19, Fig. 1) (see: column 3, lines 14-23 and column 4, lines 9-14). In addition, Colon et al. teaches a randomization routine that assigns study patients to study medications using a random number generator (see: column 5, lines 36-38).

Colon et al. fails to explicitly teach a system for ordering and tracking sample for one or more site, said sample ordering system having an electronic randomizing operation for randomizing.

Business Wire teaches Base Ten a fully integrated clinical supply chain management solution that includes inventory control, electronic batch records, manufacturing automation, trial design, labeling, packaging, randomization distribution and return management (see: paragraph 2). The Examiner considers the randomization distribution process to include an electronic randomizing operation for randomizing individual samples to one or more sites.

The motivation of combining the teachings of Business Wire within the system and method as taught by Colon et al. are discussed in the rejection of claim 1, and incorporated herein.

As per claim 8, Colon et al. teaches a database host computer (11, Fig. 1) and Internet database input forms (40, Fig. 3) used to communicate between the Internet server (13, Fig. 1) and the remote site computer (17, 18, and 19, Fig. 1) (see: column 3, lines 14-23 and column 4, lines 9-14). In addition, Colon et al. teaches a randomization routine that assigns study patients to study medications using a random number generator (see: column 5, lines 36-38).

Colon et al. fails to explicitly teach an electronic system for ordering and tracking sample supplies for one or more sites at which are being carried out a blinded, randomized testing of sample of a product, said sample ordering system having an electronic randomizing operation for randomizing.

Business Wire teaches Base Ten a fully integrated clinical supply chain management solution that includes inventory control, electronic batch records, manufacturing automation, trial design, labeling, packaging, randomization distribution and return management (see: paragraph 2). The Examiner considers the randomization distribution process to include an electronic randomizing operation for randomizing individual samples to one or more sites.

The motivation of combining the teachings of Business Wire within the system and method as taught by Colon et al. are discussed in the rejection of claim 1, and incorporated herein.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al.

As per claim 3, Colon et al. teaches a method for registrating and ordering of sample for the blinded, randomized testing of samples of a product at one or more sites, the method comprising:

i) a remotely accessing electronic database (see: column 3, lines 14-23) programmed to:

a) run real-time or batch data processes (see: column 3, lines 29-31),

b) process at least two call flows (see: column 3, lines 14-23),

c) receive and process study subject registration data (see: column 9, lines 41-43),

d) randomize subjects (see: column 3, lines 14-23), and

Colon et al. fails to explicitly teach e) determine when study numbers are fulfilled and thereafter lock out additional subjects.

However, Colon et al. teaches that the Internet network server computer (13, Fig. 1) executes the eligibility parameter of study and assigns patients to a particular study strategy according to clinical study protocol (see: column 6, lines 39-60). The Examiner considers the clinical study protocol to include the determination of a fulfilled study number so that prescriptions are not received which are outside the parameters of the study (column 6, lines 58-60). Therefore, it would have been obvious to include determining when study numbers are fulfilled and thereafter lock out additional subjects within the method and system for conducting

clinical trials as taught by Colon et al. with the motivation of providing accurate records regarding the number participants involved a particular study thereby permitting precise and correct results to the study.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al. as applied to claim 3 above, and further in view of "Base Ten Systems Completes Acquisition of Almedica Technology Group From Almedica International" by Business Wire.

As per claim 4, Colon et al. teaches a database host computer (11, Fig. 1) and Internet database input forms (40, Fig. 3) used to communicate between the Internet server (13, Fig. 1) and the remote site computer (17, 18, and 19, Fig. 1) (see: column 3, lines 14-23 and column 4, lines 9-14). In addition, Colon et al. teaches a randomization routine that assigns study patients to study medications using a random number generator (see: column 5, lines 36-38).

Colon et al. fails to explicitly teach an interactive electronic ordering and tracking system for supplying samples to one or more sites, said ordering system having electronic randomizing operation for randomizing.

Business Wire teaches Base Ten a fully integrated clinical supply chain management solution that includes inventory control, electronic batch records, manufacturing automation, trial design, labeling, packaging, randomization distribution and return management (see: paragraph 2). The Examiner considers the randomization distribution process to include an electronic randomizing operation for randomizing individual samples to one or more sites.

One of ordinary skill in the art at the time the invention would have found it obvious to include Base Ten's clinical supply chain management system as taught by Business Wire within

the method and system for conducting clinical trials as taught by Colon et al. with the motivation of serving customer more broadly, and helping them bring pharmaceutical products to market more quickly (see: Business Wire: paragraph 4).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

In related art (6,904,434) Wallach et al. teaches a method and system for enabling display of real-time clinical trial enrollment data.

In related art (6,450,054) Selker discloses a randomization mechanism for enabling randomization of a patient to one of two treatment option having different time-to-treat.

In related art (ClinPhone and InfoPro Solutions to Develop Integrated Clinical Supply Chain Management Applications) PR Newswire teaches Clinicopia software used in clinical supply chain management from forecasting of demand through planning, mobilization of required clinical materials, management of clinical inventory and the kit packaging process.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (571) 272-6773. The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RWM
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